Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of additive effect of crocin in Covid-19 patients

Protocol summary

Study aim

Additive effects of crocin on clinical symptoms, lung HRCT, total and differential WBC count and blood levels of some inflammatory factors, in Covid-19 patients admitted to Imam Reza hospital, Mashhad

Design

A Randomized, Triple-Blind, Placebo-Controlled Clinical Trial Triple masking (Participant, Investigator, Outcomes Assessor and Statistician)

Settings and conduct

Patients, after signing informed consent, will be randomly allocated to the following two groups. Placebo Group in which, patients (n=30) will receive placebo tablets and Crocin Group in which, patients (n=30) will receive Crocin 15 mg, two times per day, for 14 days. All subjects will receive the conventional anti-Covid-19 therapy and no cessation in such treatment will be considered.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Confirmed cases of Covid-19 2. Patients admitted to hospital Covid-19 general wards 3. Being 20-60 years old, of either sex. 4. Ability to sallow oral medication. 5. Patients without immunodeficiency and gastrointestinal disorders 6. Not being pregnant/breast feeding Exclusion criteria 1. Being allergic to saffron/crocin 2. Inability to swallow oral medication during admission

Intervention groups

(1) Placebo Group in which patients (n=30) will receive placebo tablets, twice a day, for 14 days. (2) Crocin Group in which, patients (n=30) will receive Crocin 15 mg, twice a day, for 14 days.

Main outcome variables

Clinical symptoms, hospital stay data and lung HRCT as well as total and differential WBC count, and blood levels of biochemical factors (CRP, ESR, LDH, TNF-α) will be collected before initiation of the treatment (day 0), and on the final day (day 14). Biochemical parameters will also evaluate one week after starting the treatment (day 7).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210203050233N1**
Registration date: **2021-04-14, 1400/01/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-14, 1400/01/25**
Update count: **0**

Registration date

2021-04-14, 1400/01/25

Registrant information

Name

RAMIN REZAEE

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2097

Email address

raminrezaee1983@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of additive effect of crocin in Covid-19

patients

Public title
Assessment of effect of crocin on Covid-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Confirmed cases of Covid-19 2. Patients admitted to hospital Covid-19 general wards 3. Being 20-60 years old, of either sex. 4. Ability to sallow oral medication. 5. Patients without immunodeficiency and gastrointestinal disorders 6. Not being pregnant/breast feeding
Exclusion criteria:
1. Being allergic to saffron/crocin 2. Inability to swallow oral medication during admission
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method (using https://www.Randomization.com-generated sequence) In this method, using website https://www.Randomization.com that generates the random number sequences, the random number sequences are determined for the required sample size (n=30 in each group). Following, after patients enter the study based on the inclusion criteria, according to the list of the random number sequences generated, individuals are assigned to one of the intervention and placebo groups, and this continues until the number of patients in each group is completed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Masking Description: Drugs will be packed and labelled . No information on the randomization schedule or the contents of drug packs will be available to patients, investigators, care providers and outcomes assessors and they will be blinded. The patients will be blinded in the sense that they do not know whether they were receiving the placebo or crocin. They randomly assign to one of the two groups. The investigators doing the interventions will be blinded as to the contents of the drug using drugs labelling. Also care providers and outcomes assessors shall be blinded as to what group the patient belongs to. One person in the project who does not belong to any of the groups of patients, investigators, care providers and outcomes assessors, will oversee on blinding method.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Institute for Medical Research Development
Street address
No. 21, Besat St., West Fatemi St., Tehran
City
Tehran
Province
Tehran
Postal code
1419693111
Approval date
2020-11-18, 1399/08/28
Ethics committee reference number
IR.NIMAD.REC.1399.251

Health conditions studied

1

Description of health condition studied
Covid 19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Cell blood count (CBC)
Timepoint
on days 0, 7 and 14
Method of measurement
CBC will be measured by auto analyzer. Differential cell counts will be performed in stained peripheral blood smear (Wright-Giemsa) under light microscope.

2

Description
serum C-reactive protein (CRP) level
Timepoint
on days 0, 7 and 14

Method of measurement
CRP serum level will be measured using standard ELISA kits

3

Description
TNF-α serum level
Timepoint
on days 0, 7 and 14
Method of measurement
TNF-α serum level will be measured using standard ELISA kits

4

Description
LDH serum level
Timepoint
on days 0, 7 and 14
Method of measurement
LDH serum level will be measured using standard ELISA kits

5

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
on days 0, 7 and 14
Method of measurement
Sedimentation Analyzer

Secondary outcomes

1

Description
A. Clinical signs and symptoms: fever, cough, dyspnea, myalgia, chill, headache, respiratory rate, weakness, chest pain, nausea, vomiting, gastro-intestinal manifestations, O2 saturation
Timepoint
On days 0 and 14
Method of measurement
Clinical signs and symptoms will be recorded using the checklist.

2

Description
Lung involvement
Timepoint
On days 0 and 14
Method of measurement
Lung radiography assessment will be performed by lung high-resolution computed tomography (HRCT).

Intervention groups

1

Description
Intervention group: In this group, patients (n=30) will receive 15 mg crocin tablet (Krocina™, made by Sami Saz Company) , twice a day, for 14 days.
Category
Treatment - Drugs

2

Description
Control group: In this group, patients (n=30) will receive placebo tablet (Containing Avicel, made by Sami Saz Company), twice a day, for 14 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital, Mashhad, Iran.
Full name of responsible person
Ramin Rezaee
Street address
Ibn Sina St., Imam Reza Hospital Square, Imam Reza Hospital
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RezaeeRA@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Institute for Medical Research Development (NIMAD)
Full name of responsible person
Dr. Reza Malekzadeh
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No. 21, Besat St., West Fatemi St.,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

National Institute for Medical Research Development (NIMAD)

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ramin Rezaee

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Dr. Ramin Rezaee is committed to presenting all the achievements of the project in accordance with the framework of the National Institute for Medical Research Development in the Islamic Republic of Iran.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available